

AC-01

Ver 1.2

General Provisions





DOCUMENT HISTORY

| Version and date of approval | Reason for revision | scope | Ultimate application date |
|------------------------------|---|-----------------|---------------------------|
| 0.0 03/07/2008 | Simplification of the structure | Entire document | 01/01/2009 |
| 1.0 9/08/20112 | Approval of version 2 of the auto-control guide Animal feed G-001 | Entire document | 9/11/20112 |
| 1.1 23/08/2013 | Correction: Registration of herd number is not applicable for feed (only Dutch version) | Point 3.7 | 22/11/2013 |
| 1.2 21/10/2016 | Update of internet link | Point 4.4 | 21/10/2016 |
| | New lay-out | Entire document | |



Table of contents

| | |
|---|-----------|
| 1. ACTIVITIES INHERENT TO THE COMPANY | 4 |
| 2. APPROVAL OR REGISTRATION OF THE COMPANY | 4 |
| 3. FOOD SAFETY MANAGEMENT SYSTEM | 4 |
| 3.1. GENERAL | 4 |
| 3.2. MANAGEMENT AND POLICY | 5 |
| 3.2.1. <i>Policy Statement</i> | 5 |
| 3.2.2. <i>Responsibility and Qualification</i> | 5 |
| 3.3. FOLLOW UP OF THE REGULATIONS | 5 |
| 3.4. DOCUMENTATION | 5 |
| 3.5. REGISTRATION..... | 6 |
| 3.6. TRAINING | 7 |
| 3.7. TRACEABILITY..... | 7 |
| 3.8. IMPROVEMENT | 8 |
| 3.8.1. <i>Corrective measures</i> | 8 |
| 3.8.2. <i>Corrective actions</i> | 8 |
| 3.8.3. <i>Precautionary measures</i> | 8 |
| 3.9. COMPLAINTS | 9 |
| 3.10. NON- CONFORMING PRODUCTS AND/OR SERVICES | 9 |
| 3.11. PRODUCT RECALL | 10 |
| 3.12. NOTIFICATION REQUIREMENT..... | 10 |
| 3.13. INTERNAL AUDIT | 10 |
| 4. GOOD HYGIENE PRACTICE | 11 |
| 4.1. INFRASTRUCTURE | 11 |
| 4.2. USE OF WATER | 11 |
| 4.3. HYGIENE ON THE WORK FLOOR..... | 11 |
| 4.4. CLEANING AND DISINFECTION..... | 11 |
| 4.5. MAINTENANCE | 12 |
| 4.6. PEST CONTROL | 12 |
| 4.7. WASTE FLOWS..... | 13 |
| 4.8. STORAGE..... | 13 |
| 5. HACCP-ANALYSIS | 13 |
| 5.1. GENERAL | 13 |
| 5.2. HACCP | 13 |
| 5.2.1. <i>HACCP Team</i> | 14 |
| 5.2.2. <i>Flowchart</i> | 14 |
| 5.2.3. <i>HACCP principle 1: hazard analysis</i> | 14 |
| 5.2.4. <i>HACCP principle 2: determination of Critical Control Points</i> | 14 |
| 5.2.5. <i>HACCP principle 3: establishing limit values</i> | 14 |
| 5.2.6. <i>HACCP principle 4: monitoring</i> | 14 |
| 5.2.7. <i>HACCP principle 5: corrective measures</i> | 15 |
| 5.2.8. <i>HACCP principle 6: verification of the HACCP-system</i> | 15 |
| 5.2.9. <i>HACCP principle 7: creation of documentation and registration</i> | 15 |

AC-01: General Provisions

1. Activities inherent to the company

In addition to the requirements contained in this chapter 'AC-01: General Provisions', each company must be able to demonstrate that their products and/or services meet the applicable requirements and have been included in the following documents:

| Activities | Documents |
|--|---|
| Production of animal feed | AC-02: Production of Animal Feed |
| Trade in animal feed | AC-03: Trade in Animal Feed |
| Storage and transshipment of animal feed | AC-04: Storage and Transshipment of Animal Feed |
| Haulage or Road Transport of animal feed | AC-05: Haulage of Animal Feed |

2. Approval or registration of the company

Any feed business operator shall, in compliance with the European Legislation (EC) No 183/2005 laying down requirements for feed hygiene ensure that establishments under their control are registered and possibly approved. Companies processing category 3 materials, and plants manufacturing feed for pet animals, handling or processing animal by-products, must also hold a specific accreditation as defined in Regulation (EC) No 1069/2009.

In Belgium, there exists an intermediate level between registration and approval, as defined in the European Regulation (EC) No 183/2005: the Authorization. This level is defined in the Royal Decree of 16 January 2006 laying down procedures for approvals, authorizations, and registrations which have been issued by the FASFC (see 'AT-01: Legislation'). An establishment performing an activity as described in Annex II to this Decree, must dispose of an FASFC approval.

An establishment performing an activity as described in Annex III of this same Decree, must dispose of an FASFC authorization.

An establishment performing an activity not included in annexes II and III of this Decree relating to production, storage, packaging and transport or trade in chemical substances or products, vegetable or animal products intended for animal feeding, must dispose of an FASFC registration.

The provisions from this Decree, are only applicable to companies established on Belgian territory.

3. Food safety management system

3.1. General

The entire policy must be focused on food safety.

A documentary system, containing procedures and/or instructions in order to satisfy all legal provisions. From this should be concluded, that the operator realizes that he is part of the food and feed chain and, must therefore, take appropriate measures in order to ensure food safety at all times. This documentary system should be maintained and continuously improved. All measures must be established in writing.

3.2. Management and Policy

3.2.1. Policy Statement

The Company must, in the context of food safety, record the policy and the concrete objectives in a written policy statement. The policy has minimum as objective, the compliance with legal obligations. Furthermore, this policy also focuses on food safety and Hygiene of animal feed. In this policy, the scope and extent of the management system should be established per activity.

The management should provide means, staff, and information, in order to allow the practical implementation of the system. The management should also assess the management system on a yearly basis. These evaluations must be recorded and archived.

Very Small Companies (VSC)

It is not mandatory for VSCs to prepare a policy statement. However, they must assess annually the measures taken in the framework of food safety.

3.2.2. Responsibility and Qualification

Only staff with sufficient experience, or having received a relevant training, are allowed to perform tasks relating to food safety.

The responsibilities and qualifications must be documented, e.g. in an organization chart, or in any other document.



Substitute in case of absence of the responsible person

If the company is adequately staffed, it may be useful to indicate the person, who in absence of the responsible person (e.g. vacation or illness) of any given post, will assume the responsibility.

3.3. Follow up of the regulations

In order to know and analyze the regulatory developments and standards applicable to its activities, the company will implement a system allowing them to maintain their level of knowledge as regards the Legislation in force.

Organizations (e.g. professional) active in the sector in which the company performs its activities, official national websites (e.g. for Belgium it is the FASFC, SPF public health, Fytoweb), are reliable sources of information for such a follow up.

3.4. Documentation

The company needs to dispose of the most recent version of the documents, whose conditions are to be observed. One must dispose of these documents in digital format or on paper.

A clear documentary system must be drawn up, with procedures and/or instructions:

- Adapted to the level of the staff;
- Readily available;

- Updated.

The company may, if they wish to do so, draw up a manual. This is a document or a collection of documents on paper or in digital form, characterizing the documentary system:

- Either a synthesis document containing a description of the system;
- or a collection of procedures and instructions, forming the system.

The documentary system includes procedures and/or instructions containing the minimum legal requirements in relation to food safety.

With each amendment to the animal feed legislation, or to activities inherent to the company, shall be examined whether the documents needs updating.

Also, a procedure is provided, describing the amendments and additions to procedures and/or instructions.

For each procedure and/or instruction, the date and version of the last modification must be indicated. Also, invalid and obsolete documents must be removed.

The most recent version of the documents should be available at locations, where they will be used. This is possibly in digital format.

The documents, must be adapted according to the complexity of the job, and to the level of staff involved.

3.5. Registration

Records of documents are required to be kept for a certain period (see below). These could be, e.g., the following documents:

- Procedures and instructions from the documentary system or manual (see 3.4);
- Purchase registrations;
- Reports of internal audits (see 3.12);
- Reports of management assessment (see 3.2.1).

Also, records relating to HACCP (e.g. upon development of a new product) and registrations relating to traceability, should be kept.

The archiving period for registrations and documents, are listed in the following table.

| Type of company | Examples (non exhaustive) | Minimum archiving period (counting from 01/01 of the following year) | Legal basis |
|--------------------|--|---|------------------------------|
| Registered company | <ul style="list-style-type: none"> - Transport operators of animal feed; - Trader in cereals. | 2 years following the expiration of related product or, failing that, minimum 2 years | RD 14/11/2003 – Art 11 |
| Authorized Company | <ul style="list-style-type: none"> - Trader in compound feed; - Producer of compound feed without coccidiostats; | 5 years with the exception of a composition of | RD |

| Type of company | Examples (non exhaustive) | Minimum archiving period (counting from 01/01 of the following year) | Legal basis |
|------------------|---|--|-----------------------------------|
| | - Producer or importer of animal feed considered to be critical. | mixtures (formulations) which should be kept for 10 years. | 21/02/2006 – Annexes I and III |
| Approved Company | - Producer of/or trader in vitamins and trace-elements (additives). - Producer of medicated animal feed. | | |

The files are sorted and classified in such a way, that, information is complete and easy to consult.

3.6. Training

Staff members should have sufficient knowledge of their assigned tasks. This can be improved by training courses.

3.7. Traceability

Traceability within the chain must be ensured, both in the upward as well as in the downward direction. Downward traceability (tracking) will ensure that products, coming from the customers, can be recalled.

Upward traceability (tracing) goes back to the origin of the product.

Example of upward (tracing) and downward (tracking) traceability

A Belgian premix manufacturer prepares a premix in which zinc oxide is incorporated. An analysis of the premix seems to indicate that a too high level of lead has been found. The manufacturer must alert his customers, who have received this premix. If necessary, the competent authorities (FASFC) will be notified (see 'AT-02: Notification Requirement'), with a possibly recall of these premixes. This is the downward traceability, also called traceability of first instance (tracking).

At the same time, the premix manufacturer tries to identify the ingredients presenting a lead contamination risk. He concludes that zinc oxide is very likely the source of the contamination. He will then examine, in which other pre-mixtures zinc oxide has been processed. This is the upward traceability, or traceability of second instance "tracing". Once again the clients and the FASFC will be notified, resulting in the recall of the batches. The supplier of the suspected zinc oxide, will also be informed. Based on the analysis, one should obviously be able to identify the real source of the lead contamination.

Traceability is based on a registration of data regarding incoming and outgoing products. Records will be kept for this purpose.

The register of incoming products consist of the following data:

- Nature of incoming product;
- Identification of product (batch or reference number allocated by the supplier);
- Quantity of product;
- Reception date of product;
- Supplier's identification (name & address of the business unit from where the product originates, or business number as recorded in the central database (in Belgium KBO number (=Kruispuntbank van Ondernemingen) / BCE (Banque-carrefour d'entreprises) number);
- Expiry date, if applicable.

The register of outgoing products consists of the following data:

- Nature of the outgoing product;
- Identification of product quantity;
- Delivery date of product;
- Identification of the customer (name and address of the buyer – additionally, when the buyer has a herd number, the herd number must be registered per delivery of compound feed).

It should also be possible to link incoming and outgoing products. Registrations must be kept thereto.

Traceability should be sufficiently accurate, but it is up to the company to decide the extent of where they want to go. The more detailed the information, the quicker and more targeted the decisions will be, in case of problems. This may, in some cases lead to fewer recalls.

3.8. Improvement

The company should continuously improve the efficiency of its system. To this end, written procedures have been established, for the implementation of corrective and precautionary measures.

3.8.1. Corrective measures

Corrective measures are taken for the purpose of eliminating any detected non-conformity. The procedures for corrective measures include:

- An examination, as to the cause of the problem, must be performed;
- Corrective measures, in order to prevent the problem from re-occurring, be determined;
- That a control, regarding the corrective measures, is performed.

3.8.2. Corrective actions

Corrective actions are taken, in order to eliminate any observed non-conformity. The procedures for corrective actions include:

- An examination, as to the cause of the problem, must be performed;
- Corrective measures, in order to prevent the problem from re-occurring, be determined;
- That a control, on the effectiveness of the corrective actions, is performed.

3.8.3. Precautionary measures

Precautionary measures are taken in order to prevent problems or complaints. The procedures for precautionary measures include:

- An investigation will be performed as to the cause of potential problems or complaints;
- Precautionary measures are taken as to prevent the problem or complaint from occurring;
- A control on the effectiveness of the precautionary will be performed.

3.9. Complaints

A complaint procedure should be in place. The complaints must be listed and assessed.

Any actions taken, and any response given to the customer, must be recorded. Depending on the severity and frequency of the complaints, amendments to existing documents, such as the Auto-control system, may be necessary.

3.10. Non- conforming products and/or services

A procedure, describing the way as to handle non-conforming products and/or services, should be in place. These are products and/or services, not satisfying the safety standards and requirements.

These products should be identified and monitored in order to prevent unintended use or delivery.

These products may be:

- Handled or decontaminated in order to satisfy the specified requirements;
- Reassigned for alternative applications;
- Rejected and/or destroyed conforming the legal provisions (see 'AT-01: Legislation').

When products have been treated or disinfected, it is necessary to control its efficiency, by making sure that there are no more non-conformities present.



Contaminated materials

The European Legislation authorizes, under certain conditions, the detoxification of contaminated materials (see document AC-00 - point 5. Definitions).

Two methods of « decontamination » may be considered:

- 1) Detoxification in an establishment, approved by the competent authorities (in Belgium: FASFC),
- 2) Contamination, intended to be reduced or eliminated through cleaning (e.g. ergot in triticale). In this case, approval of the establishment is not required.

These contaminated materials (= prior to treatment) must be subjected to a specific labeling depending on the method to be applied. (Regulation (EC) No 767/2009 – Art 20 & Annex VIII).

The concept of «contaminated materials» is closely linked to that of «undesirable substances».

For example, when taking mycotoxins in consideration, only aflatoxin and ergot may, in the Legal sense of the term, be considered as «undesirable substances». Only food, contaminated by one of these two mycotoxins may be considered as « contaminated material ». The presence of other mycotoxins in animal feed, such as, e.g. DON, does not mean that this feed should be considered as «contaminated material».



Dilution prohibition

It is prohibited to mix, contaminated materials with the same product or other products, intended for animal feed, for the purpose of dilution.

This dilution prohibition applies exclusively to material contaminated with undesirable substances within the meaning of Directive 2002/32/EC (Regulation (EC) No 767/2009), or residues of pesticides (Regulation (EC) No 395/2006 – Art 19).

For example, in the case of mycotoxins, the dilution prohibition only applies to aflatoxin and ergot. This prohibition is not applicable to other mycotoxins (Directive 2002/32/EC Annex I – Section II).

3.11. Product Recall

A recall procedure should be in place in order to, if necessary, allow a quick withdrawal of products from the market, and to inform the customers immediately as soon as there is a problem regarding the product safety.

Recalled products must be indicated in a clear manner. Also further treatment of these products should be registered. (see previous point: «non-conforming products and/or services»).

This recall procedure should at least consist of the following elements:

- Name of person responsible for the recall;
- Method of external communication.

This procedure must at least be tested annually, in order to assess the efficiency of the procedure (staff informed, updating address and phone numbers etc.). Such tests must be documented and registered.

3.12. Notification Requirement

Notification to the competent authorities is required if a serious safety risk has arising within the food chain, or where legal standards are exceeded.

The modalities for a requirement notification in document 'AT-02: Notification Requirement'.

The notification, although mandatory in other circumstances, is not required if the hazard originated within the company, but due to appropriate action, was eliminated prior to being marketed.

In this case, no animal feed containing this hazard is allowed to leave the company and TO BE marketed.

Notification is however required if the hazard originated within another company. Then there is the chance that the hazard will occur in other companies also.

It is possible that a specific hazard analysis may be required, in order to verify whether a notification should be made.

3.13. Internal Audit

The internal auditor should verify whether the internal systems and/or procedures are adequate for the safe production, trading, transport, storage or transshipment of animal feed.

This internal audit shall take place at least once a year. The reports must be registered.

Any non-conformities identified during the audit, must be eliminated by means of adequate measures and, if necessary, the documentary systems should be adapted.

4. Good hygiene practice

4.1. Infrastructure

The infrastructure of the company is designed in a way that is suitable for its intended purpose.

The company equipment is such that different products cannot unintentionally come into contact with each other, and thus avoiding cross-contamination or unintentional mix-up.

Also, the spatial lay-out of storage facilities must be such that no confusion between different products will occur upon use or delivery.

The production units and storage spaces are indicated on a floor plan. Any location that might be important for traceability, shall be identified in an unambiguous way.

4.2. Use of Water

A hazard assessment of all water within the company, coming into contact with animal feed or any other materials intended for the production / storage / transport, is to be included in the HACCP study.

The water that is used by the company, must at all times be of a quality suitable for its intended use. The company must demonstrate the way, in which it controls the potential hazards related to the quality of the used water.

The company must according to a predetermined frequency perform tests as regards the quality of water or must obtain guarantees from its water supplier, in order to ensure that the quality of the water used for activities within the company, is suitable for its intended use.

After use and/or if the water is not of suitable quality, it should be disposed of in order to avoid any danger of contamination.

This applies to both, used water as well as to rainwater.

4.3. Hygiene on the work floor

There should be clear-cut rules regarding eating and drinking at work. If necessary, separate facilities should be provided. Residues of food, beverages or packaging materials are prohibited in production and storage areas. Smoking is prohibited on company premises.

4.4. Cleaning and Disinfection

The cleaning aims at eliminating product residues and dirt forming a potential source of contamination. The cleaning method is adapted to the nature of substances to be eliminated.

When using detergents or disinfectants, the user should follow carefully the instructions for use regarding these products.

Cleaning programs should be documented and must ensure that installations are adequately cleaned.

A competent person will perform the inspections, in order to make sure that, a cleaning program is respected. These inspections should be recorded.

Products used for cleaning or disinfection shall be stored separately, in a clearly identified location, in order to avoid any risk of (accidental) contamination.

Disinfecting agents, used in buildings, installations or vehicles must:

- Be authorized in the country of the European Union where it is used, as defined in the legislation relating to biocides (Directive 98/8/EC); and
- Belong to type '4' products (disinfectants for surfaces coming into contact with food and animal feed).

As an example, for Belgium, there is a list of authorized disinfecting agents available on the website of the FPS Health, Food Chain Safety and Environment ([www.health.belgium.be/https://portal.health.fgov.be/](https://portal.health.fgov.be/)).

4.5. Maintenance

A maintenance program will ensure food safety in all equipment and installations. A report of any maintenance must be kept.

4.6. Pest Control

In company premises, measures should be taken to prevent the presence of birds and pests. To this end, pest control programs will be implemented, containing pest control methods and means. Pet animals are not allowed on company premises.

Doors and windows and any other openings should, if necessary, be resistant to pests.

Openings (e.g. for ventilation) should be designed as such that pests cannot enter the premises without compromising their actual function.

In company premises, a floor plan will be drafted, indicating those areas where pest control products are kept. The pest control plan must be reviewed annually, and its registration must be kept.

A safety information sheet regarding such means must be available.

Pest control products or biocides (e.g. rodenticides) used in buildings, installations or vehicles must:

- Be authorized in the country of the European Union where they are used, as defined in the legislation relating to biocides (Directive 98/8/EC); and
- Belonging to the applicable type of products (e.g. type '14': rodenticides).

For Belgium, there is a list of authorized biocidal products available on the website of the FPS Health, Food Chain Safety and Environment (<https://portal.health.fgov.be/>).

Insecticides, used in the context of feed protection (e.g. cereals) or used for the disinfecting the premises, such as empty storage spaces must:

- Be approved for the specific use in the country of the European Union where they are used, as is defined in the Legislation related to pesticides for agricultural used; and
- Be used according to the user instructions for that relevant insecticide.

The waiting period between the application of the insecticide and the use of treated animal feed, must be respected. If commercialization takes place before the waiting period has expired, this should be communicated to the buyer.

For Belgium, all information relating to the approval of insecticides is available on the website www.fytoweb.fgov.be/.

4.7. Waste Flows

Materials considered as waste must be visually recognized as such and immediately isolated. Waste must be disposed of on a regular basis in order to avoid accumulation.

Waste is collected and obviously separated from animal feed.

Waste must be disposed of conforming the legal provisions.

Waste water should clearly be separated from water used during production.

4.8. Storage

Products are to be stored as to ensure food safety, so that no microbiological, physical or chemical contamination occurs. Also the development of micro-organisms during storage must be prevented.

During storage, the products should be stored separated. They should be easily identifiable in order to avoid any mix-up.

The company premises are accessible to competent staff only.



Storage: separation of products

The company must determine the best way possible to separate stored products. When products come into contact with each other, a physical separation is necessary.

When products are packaged (barrels, palettes, big-bag, etc.), a space between the different products may be kept as separation, even between batches. Sometimes it may be useful to make a visible separation by marking the floor, or an identification in height using a code specific per stored product. (color, figure, symbol, etc.).

5. HACCP-analysis

5.1. General

This document adheres to the HACCP approach (Hazard Analysis of Critical Control Points). In the HACCP analysis, all stages relating to the production process are studied, and potential hazards as regards the product safety are identified. Subsequently a hazard analysis of the previously identified hazards are performed.

Control measures for these Critical Control Points (CCPs), and Attention Points (APs) are drafted. All this must be documented.

The document 'AT-04: Practical realization of an HACCP-plan' provides additional information and examples of hazard analyses for a number of processes occurring regularly in the animal feed chain.

5.2. HACCP

5.2.1. HACCP Team

The management appoints a HACCP team for the maintenance of the HACCP-system. For each team member, the following elements are set:

- Position;
- Competence;
- Responsibilities;
- Experience (training, practical experience).

The HACCP team must dispose of sufficient expertise, based on diverse disciplines for establishing and maintaining the HACCP system.

5.2.2. Flowchart

The HACCP team must identify and analyze potential hazards as regards all relevant processes.

Each process is also described in a “flow-chart”, containing all subsequent steps.

The CCPs, identified for each stage are indicated in the flow-chart.

5.2.3. HACCP principle 1: hazard analysis

A list per production step of all physical, chemical or microbiological hazards, must be made. ‘AT-04: Practical realization of HACCP-plan’ lists some examples.

5.2.4. HACCP principle 2: determination of Critical Control Points

Each hazard can be assessed based on its “severity” and “frequency”. This is how the Critical Control Points (CCPs) are determined.

Control measures can be subdivided into specific and general control measures. Multiple control measures may be needed to keep one hazard under control, and multiple hazards may be controlled with just one control measure.

1. General control measures: these are actions or activities that may be considered as being part of a basic program (e.g. maintenance, cleaning). They are not linked to critical control points (CCPs). The company must validate these general measures and verify their efficiency;
2. Specific control measures: these are actions or activities essential for the control of a significant danger. They are also linked to the Critical Control Points (CCPs). Often they are to be monitored by measuring the physical or chemical parameters (e.g. pH, moisture level). The company must control, validate and verify these specific measures, and must provide corrective measures. The Critical Control Points (CCPs) should be registered in the HACCP-plan.

These various measures are listed and they refer to the list of hazards which was drawn up according to the principle 1.

5.2.5. HACCP principle 3: establishing limit values

For each CCP, a limit value should be established. The basis on which the suitability of the limit value rests, must be demonstrated.

The limit value must be determined in order to ensure the safety of the final product.

5.2.6. HACCP principle 4: monitoring

For each Critical Control Point, relevant monitoring parameters are identified. These parameters must demonstrate, that the specific control measures achieve the target result, and that the CCP is under control.

It is important to clearly indicate for each parameter (and thus for each CCP), who does what and how this is done.

5.2.7. HACCP principle 5: corrective measures

If critical limits appear to be exceeded, then immediate and efficient action must be taken in order to remedy these hazards. These actions must deal with the cause as well as the consequences.

Here again, it is important to know, who does what and how this is done.

5.2.8. HACCP principle 6: verification of the HACCP-system

It is necessary to verify that all measures taken in the context of the first 5 HACCP principles include all activities performed by the company, which may have an impact on the food safety of the animal feed. The effectiveness of the proposed measures must also be verified.

The HACCP system is reviewed minimum once a year, and after each change in the production process, in order to verify whether the objectives of the system have been achieved.

These assessments must be registered.

5.2.9. HACCP principle 7: creation of documentation and registration

The HACCP procedures should be substantiated by documents and registrations. This will demonstrate that the measures of the above 6 HACCP principles, are effectively applied.



Practical realization of a HACCP-plan

The seven HACCP principles stated here must be applied within the company. The implementation of such a HACCP-plan is described in the document 'AT-04: Practical realization of a HACCP-plan'.